Author:	Start Date:	Completion Date:	
Natasha Henry	01/28/2021	02/02/2021	
Reviewer: LAJ, 2/3/21			
Review Comments: wp reviewed and approved. Great followup point documented that should assist our evaluation. LAJ 2/3/21 Indexing nh 05/04/21, 05/10, 5/12. 07/15/21.			

Title: *E.01.1 Interview with EPA 01/26/2021*

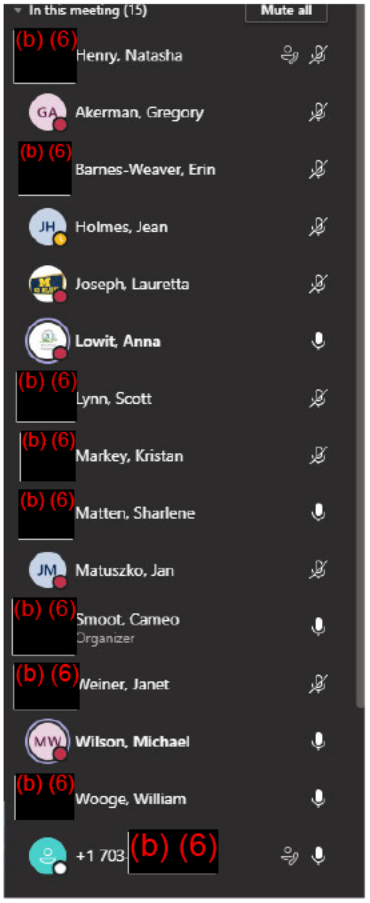
INDEX A Link: Indexed- remaining background sections.docx

Purpose: *To document information interview with the EPA Endocrine Disruptor Screening Program (EDSP) staff*

Source: *Team notes*

Source 1. Meeting Attendees

EPA name (last, first)	EPA email	Role
1. Akerman, Gregory	Akerman.Gregory@epa.gov	Acting Division Director of HED (Health Effects Division)
2. Hernandez, Connie (*Identified as the 703 number in the meeting*)	Hernandez.Connie@epa.gov	
3. Holmes, Jean	Holmes.Jean@epa.gov	
4. Lowit, Anna	Lowit.Anna@epa.gov	Senior science advisor
5. Lynn, Scott	Lynn.Scott@epa.gov	Fish biologist in role since 2011.
6. Matten, Sharlene	Matten.Sharlene@epa.gov	Biochemist. Worked on EDSP in strategic planning, budget and every aspect from 2014 through 2020. She was the last acting division director. She is now in ops as the assistant deputy ethics official. Specialized in ethics reviews.
7. Matuszko, Jan	Matuszko.Jan@epa.gov	Acting director of environmental effects and fate division
8. Markey, Kristan	Markey.Kristan@epa.gov	Chemical data scientist. Joined in 2015.
9. Smoot, Cameo	Smoot.Cameo@epa.gov	Audit Coordinator
10. Weiner, Janet	Weiner.Janet@epa.gov	Audit Coordinator
11. Wooge, William "Bill"	Wooge.William@epa.gov	Prior division director for EDSP. Been since 2006 and longest serving person



OIG Name (last, first)	Email	Role
12. Barnes-Weaver, Erin	Barnes-Weaver.Erin@epa.gov	Acting TCMPP Director
13. Joseph, Lauretta	Joseph.Lauretta@epa.gov	Program Manager

14. Wilson, Michael	Wilson.Michael@epa.gov	Team Member
15. Henry, Natasha	Henry.Natasha@epa.gov	Team Member

Source 2. Meeting Information

Tuesday, January 26, 2020, 11:00 am eastern

Microsoft Teams meeting

Join on your computer or mobile app

Click here to join the meeting

Or call in (audio only)

(b) (6) United States, Washington DC

Phone Conference ID: (b) (6)

Source 3. Calendar Invite

Link: EDSP meeting with the OIG on EPAs Implementation of the Endocrine Disruption Sc.ics

Source 4. General Discussion Questions

Link: OPP GENERAL DISCUSSION QUESTIONS v2.docx

Scope: *FWG Interview Section, Step 1*

Conclusion:

On Tuesday, January 26, 2021, the OIG team met with EPA staff via Microsoft teams to discuss general questions regarding the EDSP. (See Source 1).

The EDSP reorganization/merger is 3 months old and clear roles and responsibilities is still a work in progress [Q1]. EDSP staff reported that they were instructed to not take action on SDWA chemicals, outside of OPP [Q3]. The Comprehensive Management Plan (CMP) was updated by staff several times, but never finalized by senior management [Q4].

Staff reported that they were instructed to not utilize $5.5 million as the program had been not funded in the President's Budget [Q6].

The EPA never issued List 1 Tier 2 orders and the ICR (information collection request) was one of the longest in review with OMB (List 1 Tier 2) and the decision was made 1.5 years ago to withdraw it by EPA management [Q7].

The EPA never issued List 2, Tier 1 orders. List 2 comprised of two groups of chemicals: pesticidal active ingredients and drinking water chemicals. However, they ran out of time and could no longer make registration review timeframes. There were other decision makers that had a role.[Q10]

They don't currently have performance measures-- the last time they had them was the FY16 budget, but for the last several years they've had no APGs (annual performance goals) or measures [Q11].

Areas for follow up:

- Sharlene indicated that they will follow up on the FTE level and allocation of money. (question 2)
- Pivot policy documents (question 4)
- The team may choose to determine whether (b) (5) [redacted]. Link: Indexed- Results- IC.docx[NH Update, EPA has been unable to produce annual or internal views. See source 6 Link: A.06 - OIG information request.pdf and interview response Link: E.1.6 - PSSC - Interview Sharlene Matten (2 9 21) - Final.docx, last question, yellow highlight.]
- The team should determine whether (b) (5) [redacted] (question 7)
- The team will schedule follow up meetings with senior management

Details:

GENERAL DISCUSSION QUESTIONS

Objective- to obtain a better understanding of the EDSP progress and challenges

Introduction

Lauretta Joseph (LJ) opened the meeting and asked if there were any questions before moving to the questions. In response to an EPA question, LJ explained that OIG work will not be impacted by the change in administration as the IG role is nonpartisan and are not required to change. It was also noted that the 703 phone number in the meeting belonged to Connie Hernandez. Janet Weiner (JW) clarified that this assignment was in the OIG's annual plan.

Michael Wilson (MW) led the interview.

Current State of the EDSP

Question 1.

What is the current role and responsibilities of the EDSP?
MW also noted that the draft Comprehensive Management Plan (CMP) only projected out 2 years and would like to know what work is being done and the program hopes to achieve.

EPA response:
Kristan Markey (KM) identified that there may be a need to have specific discussion with the different groups involved within EDSP. There are many perspectives between staff and management and some differences, following the change in administration. They identified a couple of different folks to speak to, particularly OSCPP and OPP management (didn't catch all names). They also identified current EDSP staff to speak to what we are currently working on, post-reorg and before:

Rick, Ed Messina, Michael Goodis and Anne are one group. Of the 4, Anne isn't management, but can speak to the historic OPP and has a sense of what the new OPP roles are.

Joe, Karen, Scott, and Kristan can speak to the current work being done immediately and post- the reorganization.

The division directors from OPP may also have some insight.

Anna suggested that the team speak with Ed Messina and Michael Goodis. My role is the senior science advisor for the pesticides program. She is not a manager but does a lot of science coordination and cross-divisional work. EDSP is cross-coordinated with other divisions. She coordinates the science piece from a science, not management, point of view and ensures the right direction. The merger of the organization (referring to the EDSP work) is only 3 months old, so the roles and responsibilities are still a work in progress. There is clear direction from Ed and Michael on 3 documents the team needs to finish.

Sharlene agreed with Anna and said that she is a part of the team working on the 3 documents. The reorganization hasn't been the smoothest process but it's starting to come together.

MW asked to identify the 3 documents.

Kristan responded that there is a Science Policy document looking at the implementation of certain tools for Tier 1 battery and four assays (3 in-vitro and 1 in-vivo: utilization of bioactivity models as alternative to the ER binding assay, other scientific terms) On top of that, they have two response to comments documents (2015 and 2017 FIFRA SAP meetings). Those are both outstanding and support that paper. In addition to work on those 3 documents, the other key facets are to identify integration of new roles and looking at current staff, outstanding contracts and projects, etc.

Question 2:

After the Office of Chemical Safety and Pollution Prevention (OCSPP) reorganization, EDSP is shown reporting directly to the Office of Pesticide Programs (OPP) immediate office.

a. *Could you please clarify the Agency's reference to an EDSP workgroup when speaking about the EPA's endocrine disrupters work?*

Sharlene said that there are 3 different workgroups. OSCPP set up a high-level group, there's a group of senior science policy folks, and then there's a workgroup at the science staff level.

LJ explained that the team wanted to understand whether the workgroup was part of the program or separate from it. Sharlene answered that they were set up over time to feed management and support goals. It has changed over time, but they aren't independent. The 2012 CMP tried to describe the different sets of groups (science only, science policy, and then visionary at the highest levels). Right now they are sort of silent at the moment, due to the reorg.

Scott Lynn: Think about what we call those workgroups – what they were doing and the level they were working at.

b. In previous years and FY 21, the EDSP has been eliminated for funding in the presidential budget. For FY 21, what is the current enacted EDSP budget? What is the current EDSP staffing level? Other than staff, what other items are funded via EDSP? Please provide documentation.

MW asked about the full-time equivalent, or FTE level? Sharlene said that they will check and follow up on this. Janet Weiner asked for confirmation that Sharlene was not the current manager. Sharlene

responded that this is correct but she has been working on the transition and budget data. Janet said that we should here from the current manager who can speak to FY21.

[Evaluator note: The current manager is Ed Messina. The team has scheduled a follow up meeting with Ed, who was not at this meeting.]
INDEX D yellow highlight Link: Indexed- Results- IC.docx
MW stated that in prior years there were ~9 FTEs for $7.5 million. We are interested in what the money is being spent on aside from FTE. Sharlene said that there are contract dollars as a part of that amount for ~$5.5 million, but they offered to follow up on this. They haven't had 9 FTEs for a while (Kristan agreed). (See workpaper Link: B.07.2 - Correction Follow-up on OIG request for EDSP internal documents and reports - OPS response .pdf]

c. For FY 21, what is the current extramural funding level? What is this funding typically used toward?
Staff can follow up on this information.

Question 3:

With EDSP moved into OPP, what role does EDSP perform in the testing of chemicals regulated outside of OPP (e.g. the 68 SDWA chemicals on EDSP List 2)?
Kristan said that this will be a good question for Ed. There's some ongoing, more historic work on non-OPP chemicals but how that proceeds going forward may be a different story.

Scott Lynn shared that they have always pursued those chemicals, but he received recent feedback from the prior administration that the SDWA (safe drinking water act) chemicals were at the administrator's discretion and I was directed to remove certain lines on those chemicals from presentations.

EDSP's Comprehensive Management Planning

Question 4: Link: H.14 Final Indexing .docx

The draft 2018 Comprehensive Management Plan (CMP) identifies the expected "achievements" for the next two years assuming adequate funding and staffing. This planning takes EDSP to April 2020. Since April 2020, what plan has management been using to guide or task EDSP activities?

Sharlene said that they recommended to Cameo a list of office directors who could speak to this question. She was the major program lead in 2015-2016. They had a lot of draft CMPs (2015 thru 2018). She continued on: That document is not what we used to guide our decisions. We had a pivot policy. We used it to lay out our 2015 Federal Register notice. It relates to our white paper. We've been shifting to the pivot policy, and we have documents on how we used it. I wrote a draft for four years (I just kept updating it with annual accomplishments) because that's what management directed, and then we had a pivot policy. The drafts are very similar to each other. We used to do biannual reports (in response to OIG report) and then things changed politically. There was a push from staff to have things clarified but there was push back from the AA group. We definitely were working on documents.

Question 5:

Why was the draft 2018 EDSP CMP not finalized and approved?

(Discussed above. The team will follow up on this during interviews with senior management.)

Question 6:

The EPA is tasked to develop, approve, and publish EDSP CMP regularly (e.g., every 3 years). Why has the EPA not published a CMP for EDSP since 2014? Has a CMP for 2021 been initiated? Please provide a copy of the draft 2021 if it is available.

Sharlene responded: You'll have to ask individuals higher in management (AA level), though few people remain. I have speculations but I was told not to speculate. Janet: We asked Sharlene to share facts she has knowledge of but not to speculate. When you have any questions of any manager of any nature you have access to them.

(MW comment on our interest in policy and procedure.)

Sharlene clarified that there is no 2019 or 2020 CMP. They shifted resources to getting the white paper finalized because it pertained to validating tests etc. as they needed that. They shifted resources following the 2015 Federal Register Notice.
MW asked if it submitted for approval.
INDEX E Link: Indexed- Results- IC.docx
Sharlene responded that it (the CMP) was submitted for review/approval in 2017 and perhaps other interim times, through the office director (Office of Science Coordination Policy), in October 2017. There was discussion about finalizing it but that's as far as she can say. [Evaluator NH: Note, the CMP 2018 remains in draft status and was never finalized. The EPA provided the draft 2018 CMP during the entrance conference. See A.06, Source 5 email, first bullet.]
INDEX B Link: Indexed- Results- IC.docx
Link: Indexed- Results-EDSP.docx **Ref A** Kristan: On multiple occasions, I was directly instructed to adhere to the reality of zero funding in the President's Budget even though we were fully funded by Congress.
Bill Wooge: Agreed with Kristan. There was this weird tension.
Janet: There are staff not aware of the discussion.
Kristan: That was my factual knowledge – to not plan for the future based by the President's Budget.
Sharlene: I received the same direction but pushed back and said I'm not wasting $5.5 million.
Kristan: We took it upon ourselves for contingency funding to use as a guide for three years to propose recommendations when funding was piecemeal restored, given congressional recommendations.

List 1 – Tier 2 Test Orders

Question 7:

On June 29, 2015, the EPA published Weight of Evidence conclusions of the Tier 1 data and recommendations for Tier 2 testing. The EPA identified that 18 pesticides needed additional Tier 2 testing. In the 2014 EDSP CMP, these Tier 2 test orders were to be issued between 2014-2016.

a. *Describe the role of OPP's Hazard and Science Policy Council (HASPOC). Did HASPOC evaluate the June 29, 2015 conclusions of the Tier 1 data and recommendations for Tier 2 testing? If so, does the HASPOC document their decisions for each pesticide? Please provide any relevant documentation.*

Jean Holmes: In EFED we did evaluate those and we sent you the draft document completed about 1.5 years ago. We are going to finalize it when the NAMS (New Approach Methodologies) document is

completed, and the policy document. We will include that for public comment. The Science Policy Council is not mirrored in EFED.

MW: Will it go out for external peer review? Jean: It will go in the docket for comment.

b. *Did EPA issue any of List 1 – Tier 2 test orders (MEOGRT, LAGDA, CTA, and Special Androgen Test)? If so, please provide documentation.*

MW: Are there only two CTAs left to be done?

Greg Akerman: The CTAs are difficult studies to do so we had preliminary work/data done, but we have not completed the definitive studies yet.

Bill W: It's not my understanding that we ever officially issued List 1 Tier 2 orders, correct? I was working on the ICR (Information Collection Request) with OMB and it was in a holding pattern for a long time. We never issued List 1 Tier 2 orders. I have the honor of having the longest ICR in review with OMB (List 1 Tier 2) and the decision was made 1.5 years ago to withdraw it. Greg: You are correct, Bill. Bill: From the EDSP side, we never issued List 1 Tier 2 orders.

MW: Did the ICR include wildlife or just CTA? Bill: It did not include CTA. Sharlene: We have a copy of the ICR. (MW said he would like that.) Bill: I can send a link to the docket. Cameo: I worked on that and can provide the prior and current document. Sharlene: A lot of folks had a hand in it. You'll have to speak to upper management on the decision to pull it. It wasn't OMB who pulled it; it was upper EPA management.

Question 8:

In Sept. 6, 2019, the Environmental Fate and Effects Division (EFED) issued a memo (white paper) on the re-evaluation of EPA's 2015 List 1- Tier 2 recommendations that concluded that no additional Tier 2 wildlife data (i.e., MEOGRT or LAGDA) is needed.

a. *Did the HASPOC assess EFED's Sept. 6, 2019 re-evaluation EDSP's List 1 – Tier 2 recommendations?*
b. *Was EFED's re-evaluation peer reviewed by FIFRA SAP?*
c. *Has this EFED re-evaluation decision been made public?*
d. *Is EFED's re-evaluation the final decision for Tier 2 wildlife testing for List 1?*

(MW: OPP actions on white paper.)

Jean: It's a draft document. As we looked at the comments, there are some tweaks to make. So far, there won't be any decision changes in the document. Just to step back, on the Tier 2, when we did the evaluation it was to determine, using a risk-based method, do we need Tier 2 or targeted data? The document lays out our analysis and conclusions. We completed the document a little over a year ago.

Sharlene: During the reorg and the integration of folks from the science staff, there may be additional input from upper managers on that. We haven't discussed those documents/comments post-reorg/transition. It's potentially part of the reorg/integration discussion we mentioned in questions 1-3.

Question 9:

On Sept. 17, 2019, Office of Science Coordination and Policy (OSCP) provided scientific and policy analysis comments on the white paper. What actions, if any, did OPP take regarding OSCP/EDSP's comments on the white paper?

(Discussed immediately above.)

List 2 – Tier 1 Test Orders

Question 10:

The final EDSP List 2 was published on June 14, 2013 (78 FR 35922). The EDSP List 2 originally contains 109 Chemicals (41 pesticides and 68 SDWA chemicals). The 2014 EDSP CMP states EPA will incrementally issue these test orders over 3 years from 2014-2016. Furthermore, the 2014 EDSP CMP identifies it will take another year for the EPA to review the data, but also identifies a period of activity spanning 2016-2019.

c. *Did EPA issue these List 2 - Tier 1 test orders for the 107 chemicals/pesticides remaining on the list? If not, please explain why the EPA has not issued these List 2 - Tier 1 test orders?*

Bill: List 2 was comprised of 2 groups of chemicals. The first was pesticide active ingredients scheduled for registration review. Time had progressed and put those on list 2 because we needed to align with the time needed for the registration review process. AS time went on, that window for that need of information had passed, so those chemicals were no longer in play. The other group were drinking water chemicals to which a substantial population is exposed to. We worked with our sister office in OW to create that list and make that factual finding on exposure. When we went out with list 2 for the DW chemicals, OW came back with a 400-500-page document explaining their rationale for including those chemicals. So, time blew list 2 out of the water. We could no longer make registration review timeframes and things increased with OW.

Sharlene: Short answer is no. None were issued. There were other decision makers that had a role.

(MW noted white paper comment on one risk assessment not a substitute for another.)
Sharlene: Are you talking about the 2013 FRN on process for SDWA chemicals? MW: No (quoted white paper, I believe- note from evaluator- unsure). Sharlene: If you need more clarification we can respond in writing. The short answer is that the statutes are different.

Anna: This is an important thread for the IG to pull on as you start to do interviews on a more granular level because it's a complex question you're asking on science and policy. It also has to do with the merging/reorg.

Bill: There are a lot of different opinions.

d. *In the 2009 House Report #111-180, Congress instructed the EPA to issue 25 test orders per year from List 2 starting in FY'11. Has the EPA complied with this direction from Congress?*

(Discussed above.)

INDEX C Link: Indexed- Results- IC.docx Link: Indexed- Results- IC.docx

Performance Measures

Question 11:

Are performance measures used to track the progress of the EDSP? Please provide documentation of EDSP performance measures and results from 2014-2020.

Bill W responded that they don't currently have performance measures. He believes that the last time they had them was the FY16 budget, but the last several years they've had no APGs (annual performance goals) or measures.

Janet said to send list of follow-up questions/needs to Janet and Cameo.

The meeting adjourned after 60 minutes.

INDEX A Link: Indexed- remaining background sections.docx

GENERAL DISCUSSION QUESTIONS

Office of Inspector General (OIG) meeting with Environmental Protection Agency (EPA) Endocrine Disruptor Screening Program (EDSP)

Tuesday, January 26, 2020, 11:00 am eastern
Microsoft Teams

Objective- to obtain a better understanding of the EDSP progress and challenges

Questions

Current State of EDSP

1. What is the current role and responsibilities of the EDSP?
2. After the Office of Chemical Safety and Pollution Prevention (OCSPP) reorganization, EDSP is shown reporting directly to the Office of Pesticide Programs (OPP) immediate office.
    a. Could you please clarify the Agency's reference to an EDSP workgroup when speaking about the EPA's endocrine disrupters work?
    b. In previous years and FY 21, the EDSP has been eliminated for funding in the presidential budget. For FY 21, what is the current enacted EDSP budget? What is the current EDSP staffing level? Other than staff, what other items are funded via EDSP? Please provide documentation.
    c. For FY 21, what is the current extramural funding level? What is this funding typically used toward?
3. With EDSP moved into OPP, what role does EDSP perform in the testing of chemicals regulated outside of OPP (e.g. the 68 SDWA chemicals on EDSP List 2)?

EDSP's Comprehensive Management Planning

4. The draft 2018 Comprehensive Management Plan (CMP) identifies the expected "achievements" for the next two years assuming adequate funding and staffing. This planning takes EDSP to April 2020. Since April 2020, what plan has management been using to guide or task EDSP activities?
5. Why was the draft 2018 EDSP CMP not finalized and approved?
6. The EPA is tasked to develop, approve, and publish EDSP CMP regularly (e.g., every 3 years). Why has the EPA not published a CMP for EDSP since 2014? Has a CMP for 2021 been initiated? Please provide a copy of the draft 2021 if it is available.

List 1 – Tier 2 Test Orders

7. On June 29, 2015, the EPA published Weight of Evidence conclusions of the Tier 1 data and recommendations for Tier 2 testing. The EPA identified that 18 pesticides needed additional Tier 2 testing. In the 2014 EDSP CMP, these Tier 2 test orders were to be issued between 2014-2016.
    a. Describe the role of OPP's Hazard and Science Policy Council (HASPOC). Did HASPOC evaluate the June 29, 2015 conclusions of the Tier 1 data and

recommendations for Tier 2 testing? If so, does the HASPOC document their decisions for each pesticide? Please provide any relevant documentation.

b. Did EPA issue any of List 1 – Tier 2 test orders (MEOGRT, LAGDA, CTA, and Special Androgen Test)? If so, please provide documentation.

8. On Sept. 6, 2019, the Environmental Fate and Effects Division (EFED) issued a memo (white paper) on the re-evaluation of EPA's 2015 List 1- Tier 2 recommendations that (b) (5) [redacted]
    a. Did the HASPOC assess EFED's Sept. 6, 2019 re-evaluation EDSP's List 1 – Tier 2 recommendations?
    b. Was EFED's re-evaluation peer reviewed by FIFRA SAP?
    c. Has this EFED re-evaluation decision been made public?
    d. Is EFED's re-evaluation the final decision for Tier 2 wildlife testing for List 1?

9. On Sept. 17, 2019, Office of Science Coordination and Policy (OSCP) provided scientific and policy analysis comments on the white paper. What actions, if any, did OPP take regarding OSCP/EDSP's comments on the white paper?

List 2 – Tier 1 Test Orders

10. The final EDSP List 2 was published on June 14, 2013 (78 FR 35922). The EDSP List 2 originally contains 109 Chemicals (41 pesticides and 68 SDWA chemicals). The 2014 EDSP CMP states EPA will incrementally issue these test orders over 3 years from 2014-2016. Furthermore, the 2014 EDSP CMP identifies it will take another year for the EPA to review the data, but also identifies a period of activity spanning 2016-2019.
    a. Did EPA issue these List 2 - Tier 1 test orders for the 107 chemicals/pesticides remaining on the list? If not, please explain why the EPA has not issued these List 2 - Tier 1 test orders?
    b. In the 2009 House Report #111-180, Congress instructed the EPA to issue 25 test orders per year from List 2 starting in FY'11. Has the EPA complied with this direction from Congress?

Performance Measures

11. Are performance measures used to track the progress of the EDSP? Please provide documentation of EDSP performance measures and results from 2014-2020.

Author: MHW	**Start Date:** 2/3/21	**Completion Date:** 2/8/21; wp not entered into AAW for review until 3/31/21
Reviewer/Date:	LAJ, 4/12/21	
Review Comments: wp reviewed and approved. LAJ		
Edited by: Indexing NH 05/18/21.		

Title: Interview – Bill Wooge (2 3 21)
Workpaper: E.1.2

Purpose: To document the OIG's interview of Bill Wooge (i.e., former EDSP Director)

Date / Time / Location: Wed., Feb. 3, 2020/ 3:00 pm – 4:00 pm/Microsoft Teams Meeting

Participants/Invitees:

OIG / Office of Evaluation (OE)
Lauretta Joseph, Project Manager, OE/Toxics, Chemical Mgt. and Pollution Prevention (TCMPP)
Natasha Henry, Auditor, OA&E/TCMPP
Michael Wilson, Toxicologist, OA&E/TCMPP

Office of Chemical Safety & Pollution Prevention (OCSPP)/Office of Pesticide Programs (OPP)
William (Bill) Wooge

Sources:

Source 1: OIG Interview Questions for Bill Wooge
Filename: E.1.2 - Source 1 - wooge_interviewquestions.docx

Source 2: OSCPP 5 22 2019 Memo for Record to Withdraw List 1 Tier 2 ICR from OMB
Filename: E.1.2 - Source 2 - MFR_EDSP_List1_Tie_2_ICR_Withdrawal_for_signature.docx

Source 3: EPA's ICR Addendum for List 2 – Tier 1 (Dated June 14, 2013)
Filename: E.1.2 - Source 3 - EPA-HQ-OPPT-2013-0275-0001.pdf

Source 4: List 1- Tier 2 ICR
Filename: E.1.2 - Source 4 - 80 FR 45974.pdf

Scope: The scope of this workpaper is limited to documenting the OIG's discussion with Bill Wooge on Feb. 3, 2021.

Conclusions:

- BW stated that EDSP's customer was OPP.

- As the former EDSP Director, BW made the recommendation to more EDSP into OPP.
- BW suggested OPP should require Tier 1 EDSP screening data for all registration applications for new active ingredients.
- EDSP was ready to go with List 2, but OSCPP lacked the "institutional will" to follow through with issuing test orders for List 2 – Tier 1.
- On May 22, 2019, EPA requested the ICR for List 1 – Tier 2 to be withdrawn from OMB.
- EPA sent a ICR for List 2 – Tier 1 to OMB on June 14, 2013.
- In OPP's opinion, "endocrine disruption can be elucidated" by the normal toxicity studies already generated and collected for a pesticide registration.
- According to BW, EPA is are not going to focus on SDWA chemical. EPA is going to only focus on all active ingredients.

Results:

LJ – Started the interview by describing to BW that we want this interview to be less formal and more of a conversation about the topic.

LJ – Asked BW to describe his prior role with EDSP (i.e., OIG question 1a).

BW – I started working for EPA in 1991. I worked as a special assistant in OPP's human health risk assessment division (Analyst Note: currently OPP/HED). I started working in EDSP in 2012. I was the longest serving EDSP employee when it was moved out of OSCP. I served as the acting EDSP director from about Aug 2017 to Feb. 2020.

LJ – Asked BW about how EDSP fit into EPA structure organizationally (i.e., OIG question 1b).

BW – First of all, OCSPP is currently split into three offices: TSCA, OPP, and OPS? BW was not sure of the last office's name, but it deals with operations. BW explained that the old OCSPP also had three offices, but the third offices was named the Office of Science Coordination and Policy (OCSP). BW explained that OCSP was divided up into three main areas that addressed the following areas: operations, exposures assessment (i.e., EDSP), and Science Peer Reviews/FIFRA FACA committees. BW stated that EDSP was in the Exposure Assessment Coordination and Policy Division. BW explained that this was a very complicated name, but the division was basically the EDSP. BW stated that EDSP's customer was OPP.

BW – My first job in OSCP in 2008-09 was to run a FIFRA FACA committee. The FIFRA science advisory panel reviewed the tier 1 battery methods that were developed.

LJ – In your opinion, where do you think EDSP should housed in EPA since it screens both pesticide and SDWA chemicals (i.e., OIG question 1c).

BW – Opinion? You want my opinion. (Note: (b) (5) [redacted].

LJ – Yes. We want your opinion. The OIG rarely attributes an opinion or statement during an interview to an individual in an OIG report.

(Analyst Note: (b) (5) [redacted])

BW – When EDSP initially developed and validated the Tier 1 battery of EDSP tests, [Analyst Note: In 1998, EPA adapted EDSTAC Recommendations. EPA issued Final Tier 1 tests on 10/21/09. EDSP then issued List 1 in 4/14/09] this surge in science came with the initial development of high through put assays and computational toxicology. This advancement in science occurred when EDSP issued List 1 – Tier 1. [Analyst Note: EDPS published the EDSP21 Workplan on 9/30/2011 – Plan of High Through-put Assays and Computational Models] We recognized that to screen all 600-900 active pesticides was going to be monumental task. I realized at the time that I had just created lifetime employment for myself.

BW – Since the tier 1 battery are expensive to perform at about $1.2 million per chemical/pesticide, the cost to screen all active ingredient would be a massive amount.

Link: B.03.1 EDSP Tiered Assessments .docxBW – You have to remember that Tier 1 is for screening. It evaluates if a chemical has the "potential to interact" with the endocrine system. By contrast, Tier 2 represents the "long-term, multi-generation studies". Tier 2 test are used to develop the "dose- response curve" for use in the risk assessment.

BW – EPA never got to Tier 2. EPA "changed horses in mid-stream". EPA changed paths from using the Tier 1 screening battery and Tier 2 animal studies to the use of high through put assays and computational toxicology.

BW – FIFRA grants EPA the authority to require the pesticide manufacturer's to provide data to get and maintain their pesticide registration. Other environmental statues do not have this data requirement (e.g., SDWA). This can be seen in List 1 – Tier 1. We started with something like 67 active pesticides and inerts. So, some pesticide manufacturers decided to voluntarily cancel their pesticide's registration to avoid having to conduct the Tier 1 testing. Likewise, the chemical manufacturers' of the inerts did not want to conduct the Tier 1 testing either. So, there are a lot of chemical that have dual use (i.e., chemical use outside of FIFRA and within FIFRA). An example of a dual use chemical is your phthalates. They are used as both as inert ingredients and outside of FIFRA. So these chemical manufacturer's avoided having to conduct Tier 1 testing by signing an agreement that they will not sell it for use in pesticide formulations. Between cancelled registrations and decline to sell inert ingredients, the List 1 chemical fell to something like 52.

BW – When you get to List 2, the non-FIFRA chemicals (i.e., SDWA chemicals), how is EPA going to compel non-FIFRA chemical manufacturer's to generate the Tier 1 data? SDWA does not have provisions to compel data collection from the chemical manufacturers.

BW - We had technology changing while we still trying to collect data using the old methodology. So EPA "road two horses". "One did not get there --- or drowned."

BW – As the former EDSP Director, I made the recommendation to more EDSP into OPP.

MW – Just to clarify, Tier 1 testing is only to screen chemicals. While Tier 2 are mulit-generation animal studies to generate dose response curves for regulator decisions.

BW – "You nailed it." Tier 1 is screening, and Tier 2 is testing to identify the dose-response. However, we never issue any Tier 2 test orders.

LJ – Could you describe how the EDSP data is incorporated into the pesticide registration review process?

BW – The original statue requires EPA to test all active ingredients. This means OPP needs to test all active pesticides and inerts. Inerts are in every pesticide product and could cause risk by themselves. (b) (5) [redacted] (missed in my OIG notes – interview to fast to capture everything). (b) (5) [redacted] (b) (5) [redacted]

BW – The EDSP Tier 1 and Tier2 data was intended to provide information for EPA registration review. These are the pesticides that already have registrations. (b) (5) [redacted] EPA has about 6 -7 new pesticides newly registered each year. If EPA does not collect endocrine data during the initial registration, it just gets put off and the pool of pesticide registration needing EDSP screening increases. If the initial registration of new active ingredients is required to conduct the EDSP Tier 1 screening, EPA could avoid this problem (i.e., conduct the EDSP screening during the pesticide application process).

BW – OPP signed off on conducting List 2 – Tier 1 test orders. However, Link: Indexed-Results-EDSP.docx **Ref B** EDSP was ready to go with List 2, but OSCPP lacked the "institutional will" to follow through with issuing test orders for List 2 – Tier 1. Link: Indexed-EDSP lists and Tiers.docx Link: Indexed- Results-EDSP.docx Link: Indexed- Results-EDSP.docx **Ref A** EPA never issued any List 2 test orders (i.e., either Tier 1 or Tier 2). You have to remember the burden that collecting this List 2 – Tier 1 data. Specifically, the burden on the registrants to generate the data, and the burden on EPA staff to review and evaluate the data once submit.

> [Analyst Note: BW did not include the burden it takes to issue the ICR and test orders to all the registrants.]

MW – In the 2009 in Congressional budget language, EPA was instructed to issue 25 test orders per year from List 2 starting in FY'11 (b) (5) [redacted]

BW – Link: Indexed- Results-EDSP.docx **Ref C** You have to remember that List 2 was to generate data for the pesticide registration review program. In 2007-08, we knew which pesticides needed data for their pending registration reviews. However, by the time List 2 was issued in 2013, we still needed time to issue the Tier 1 test orders, needed to allow time for the registrants to generate the data, needed time to allow EPA to review and analyze the data. Then you would have to do the process over again to collect Tier 2 data containing the dose-response data for the pesticide's risk assessment. So "List 2 became stale because we did not act on it".

BW – In 2015, the EDSP was moving to make the collection and use of EDSP data practicable. ESDP issued the "Pivot Policy" in the Federal Register. The Pivot Policy identifies that the Agency will allow the use of validated high-throughput *in vitro* assays and computational models in the EDSP.

MW – Can you identify where this is documented?
INDEX A Link: Indexed- Results- IC.docx
BW – Sure. BW proceeds to share his computer screen and opens EDSP's Federal Register Notices web page [https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-federal-register-notices]. BW looks through the list and identifies the Federal Register issued on June 19, 2015.

> [Analyst Note: This is 80 FR 35350. This FR describes how EPA is planning to incorporate an alternative scientific approach to screen chemicals for their ability to interact with the endocrine system.]

MW – Can you identify which of the 11 tests in the Tier 1 battery have been replaced by NAMs?

BW – BW pulls up the list of Tier 1 tests on his computer screen. He identifies that EPA has accepted three alternative methods (i.e., NAMs) for OCSPP 890.1250, OCSPP 890.1300, and OSCPP 890.1600. EPA is proposing alternative methods for OCSPP 890.1150 and OCSPP 890.1550). NAMs for the remaining 6 Tier 1 EDSP battery are still in development.

BW – BW stated that EPA did not have a thyroid test in Tier 1. EPA is working on developing a test to evaluate disruption of the thyroid pathway.

> [Analyst Note: The 2014 CMP identifies that the following Tier 1 tests evaluate the hypothalamic-pituitary-thyroid axis: OCSPP 890.1100 Amphibian Metamorphosis (Frog), OCSPP 890.1450 Pubertal Development and Thyroid Function in Intact Juvenile/Peripubertal Female Rats, and OCSPP 890.1500 Pubertal Development and Thyroid Function in Intact Juvenile/Peripubertal Male Rats (see 2014 CMP – doc pages 26 and 27). Therefore, BW statement that EPA's Tier 1 tests do not evaluate thyroid disruption appears to be inaccurate.]

MW – On a different topic, EPA send the List 1 – Tier 2 Information Collection Request (ICR) to OMB on Aug. 3, 2015 (i.e., 80 FR 45974) in order for EPA to issue the List 1 – Tier 2 test orders. During the Jan. 26, 2021 interview, the OIG learned that OMB did not act on the ICR for 4 years. Can you characterize what was happening between EPA and OMB for those four years? Do you have any records of how or why this ICR was terminated?

BW – An ICR is required when the government requires the public to provided information or data to the government for more than 7 people. The amount of paper to get an information collection approved by OMB is extensive. EPA has to develop a detailed plan for how EPA is going to use the data. EPA has to explain to OMB and get them to understand the necessity for the data. EPA believed with the more chemicals being tested, the price should drop. At the time, only a few laboratories were step up to perform these new studies. EPA had to rounds of public comments on the List 1 – Tier 2 ICR.

BW – In my opinion, (b) (5) [redacted]

Link: Indexed- Results-EDSP.docxMW – I am having a difficulty understanding how in 2015 EFED recommends that 17 List 2 pesticides need Tier 2 wildlife, but just 4 years later conducts a re-evaluation of the same data and comes to the completely opposite conclusion that none of the 17 List 2 pesticides need Tier 2 wildlife testing. It's the same data set but completely different conclusions.

BW – The retrospective analysis of these 17chemicals concluded that the available non-EDSP data was adequate to characterize the potential endocrine disruptor risk. EFED no longer needed the Tier 2 data to complete the pesticide review.

BW – (b) (5) [redacted]

MW – I am interested in knowing how List 1 – Tier 2 ICR ended. Who made the decision to end it? Did OMB end it? Is there a record stating the reason OMB returned the ICR after 4 years?

BW – Actually, it was EPA that asked for the List 1 – Tier 2 ICR to be withdrawn. Let me find the MFR (i.e., stands for "Memorandum for Record") on my computer. After about a minute looking on his computer, BW found it and forwarded a copy of the List 1 – Tier 2 MFR (MFR Dated May 22, 2019) to LJ (see source 2). BW state that his copy is not signed. If the OIG wanted a signed version of the MFR, we could get if from Haley's (Analyst Note: Not sure who this person is).

MW – I don't think we need to get the signed version of the MFR. It not like we are taking someone to court.

MW – You know I am going to ask about the ICR for ICR for the List 2 – Tier 1 test orders. Do you know if EPA send an ICR to OMB? And whether it was approved?

BW – The List 2 – Tier 1 ICR was problematic. We had to develop a new policy and procedures for the SDWA chemicals (i.e., the non-pesticide chemicals). We learned that the conducting EDSP testing using the List was very resource intensive. We should gather data like TSCA which uses rolling issuance of data call-in notices (DCNs) instead of EDSP use of list (i.e., we used a batch process with is inefficient). EPA's ICR for List 1 – Tier 2 is in the docket.

MW – Yes. That is a stand OPP answer is that all the records are in the docket. However, if you don't know the exact docket number for the task/project in question, you can't find it.

BW – Find the docket number is no problem. Just go to the EDSP webpage listing the Federal Registers (FR) issued and the FR will have the docket number you need. BW pulled up the EDSP webpage listing the Federal Registers and identified the June 14, 2013 FR with the ICR Addendum for List 2 – Tier in the summary description.

> [Analyst Note: EPA issued the ICR Addendum for List 1 - Tier 2 on June 14, 2013 (see 78 FR 35903) – (see source 3)]

BW – I believe OMB approved the ICR for List 2 – Tier 1. On second thought, maybe. I can't be sure. (b) (5) [redacted] You know, EPA was switch horse by this time and no longer needed the List 2 – Tier 1 data.

BW – EPA was working to change the technology. List 2 – Tier 2 would be so expensive to complete. Issuing test orders takes a long time to complete. Then it takes another 2+ years to get the data.

> [Analyst Note: EPA List 1 – Tier 2 ICR states that the estimated number of respondents would be 100 and the total estimated cost would be $5,861,023 (see source 4). This works out to $586,000 per respondent.]

BW – There other issues that come up. One of the chemicals has six isomers. So you have to work with the manufacturer to identify which one of the isomers you want tested.

BW – List 2 was even more complicated than List 1. List 2 has the SDWA drinking water where you had to show exposure. The SDWA statue does not have data call in provisions to allow EPA to compel manufacturer to generate and provide this data to EPA.

BW – In order to conduct EDSP testing on SDWA chemicals, EPA have to show/document exposure. You have to have municipalities look for it in the drinking water. However, a lot of the exposure data is known through modeling; not actual laboratory results of drinking water samples. This is the difference between modeling data and monitoring data. Monitoring data is hard to get and it requires that you actually have a laboratory method for analyzing the chemical from drinking water.

BW – EPA Toxic Release Inventory (TRI) showed that one chemical had 700 manufacturers so that EPA would have to issue 700 test orders for just that one chemical.

BW – Not only does the SDWA statue no have data call in provisions, if data is collected, SDWA has no provisions to protect the data (e.g., like CBI).

MW – With EDSP being within OPP, how is EDSP going to address non-pesticide chemicals?

BW – We are not going to focus on SDWA chemical. We are going to focus on all active ingredients. Furthermore, the FQPA required EPA to test for estrogen disruption, the other endocrine systems [i.e., androgen, thyroid, steroidogenesis, and others] are at our discretion.
BW – I have another meeting I need to attend at 4 pm. (b) (5) [redacted]

LJ – I just wanted to ask whether there is a functioning EDSP program anymore beyond just pushing the new technology?

BW – In OPP's opinion, "endocrine disruption can be elucidated" by the normal toxicity studies already generated and collected for a pesticide registration. If would have been useful if OPP had told OCSP 12 years ago that the "current toxic data is sufficient" to evaluate the endocrine risk. If you talk to Anna, OPP has adequately evaluated the endocrine disruption potential of about 95% of the active ingredients. We are all just trying to do the right thing.

BW – (b) (6) [redacted]. (b) (5) [redacted] (b) (6), (b) (5) [redacted]

LJ – Are you available for another meeting for us to continue talking to you?

BW – Yes. Just not this week. I am full booked Thursday and Friday. Just get on my schedule for next week.

LJ, NH, MHW – Thanks. Good-bye.

BW – Good-bye.

Questions for meeting with Past EDSP Director
Wednesday, February 3, 2020 at ____
Microsoft Teams Meeting

Evolution of EDSP

1. During the entrance conference, it was noted that you were the longest serving staff in the EDSP. Please remind us of your current and previous roles in EDSP.
    a. Please discuss the previous organizational structure of the EDSP.
    b. Would you discuss the evolution of the EDSP structure within the EPA organizationally?
    c. In your experience, where should EDSP be housed to best serve the Agency?
2. Please discuss the status of the incorporation of EDSP into the pesticide registration review process.
3. The draft 2018 Comprehensive Management Plan (CMP) identifies the expected "achievements" for the next two years assuming adequate funding and staffing. This planning takes EDSP to April 2020. Since April 2020, what plan has management been using to guide or task EDSP activities?
4. To your knowledge, why was the draft 2018 EDSP CMP not finalized and approved?
5. Is there a policy or procedure that guides the process for management's review and approval of the CMP?

List 1 – Tier 2 Test Orders

6. EPA has not issued any test orders. On Aug. 3, 2015, EPA provided OMB with the ICR for the List 1 – Tier 2 test orders.
    a. Please describe EPA's actions to get OMB's approval.
    b. What was OMB's reasons for not approving EPA's ICR? Any records documenting OMB's reasons for denying or returning of the ICR?
    c. When did OMB formally deny/return the ICR to EPA? Any records documenting OMB's denial/return of ICR?

7. On Sept. 17, 2019, Office of Science Coordination and Policy (OSCP) provided scientific and policy analysis comments on the white paper. What actions, if any, did OPP take regarding OSCP/EDSP's comments on the white paper?

List 2 – Tier 1 Test Orders

8. The final EDSP List 2 was published on June 14, 2013 (78 FR 35922). The EDSP List 2 originally contains 109 Chemicals (41 pesticides and 68 SDWA chemicals). The 2014 EDSP CMP states EPA will incrementally issue these test orders over 3 years from 2014-2016. Furthermore, the 2014 EDSP CMP identifies it will take another year for the EPA to review the data, but also identifies a period of activity spanning 2016-2019.

Commented [JL1]: Followup question about EDSP data connection

Commented [JL2]: (b) (5) [redacted]

a. Please explain why EPA has not issued these List 2 - Tier 1 test orders for the 107 chemicals/pesticides remaining on the list?
b. With EDSP moved into OPP, what role does EDSP perform in the testing of chemicals regulated outside of OPP (e.g. the 68 SDWA chemicals on EDSP List 2)?
c. Specific to the SDWA chemicals, has a determination been made to not conduct EDSP Tier 1 testing?

Commented [JL3]: Follow-up question- who made this determination and when was it made
Follow-up- does this change have to go through Federal Register

Commented [JL4]: (b) (5) [redacted]

9. In the 2009 House Report #111-180, Congress instructed the EPA to issue 25 test orders per year from List 2 starting in FY'11. Why has the EPA not complied with this direction from Congress?

10. Overall, what have been the barriers to EPA conducting the testing that Congress mandated?

Performance Measures and Reviews

11. Although the program was cancelled in the presidential budget the last four years, it has subsequently been funded by Congress each year. As a funded program, why does the EDSP not have any current performance measures?

12. Once the program received funding from Congress each year, did the OCFO provide you with guidance and/or procedures for how your program should proceed such as how you would meet ongoing implementation requirements, as well as data collection, annual measurement and annual reporting requirements?

13. According to the corrective actions agreed to with the OIG for the 2011 report, EDSP was to conduct annual reviews. Provide an overview of the most recent annual review, including any challenges, and major findings.
    a. How frequently are these reviews conducted?
    b. Have there been communication challenges that were noted between staff and upper management?
    c. When is the next review scheduled to be conducted?

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 22, 2019

MEMORANDUM FOR RECORD

TO: Angela Hofmann, Director
Regulatory & Information Coordination Staff (RICS)
Office of Program Management Operations (OPMO)
Office of Chemical Safety & Pollution Prevention (OCSPP)

FROM: Hayley Hughes, Director
Office of Science Coordination & Policy (OSCP)
Office of Chemical Safety & Pollution Prevention (OCSPP)

RE: Withdrawl of EDSP List 1 Tier 2 Information Collection Request from the Office of Management & Budget (OMB)
EPA ICR #2479.01, OMB #2070-(NEW)

The Office of Science Coordination and Policy (OSCP) is requesting that the Endocrine Disruptor Screening Program (EDSP) List 1 Tier 2 Information Collection Request (ICR) be withdrawn from OMB. EPA submitted the EDSP List 1 Tier 2 ICR to OMB for review and approval in accordance with the Paperwork Reduction Act (PRA) on August 3, 2015. The Agency is reassessing the need for Tier 2 data on the 18 EDSP Tier 1 chemicals[1] that were initially recommended for EDSP Tier 2 studies. After the reanalysis, should EPA determine that additional EDSP Tier 2 studies are required, we will pursue a vehicle for data collection at that time.

[1] The results of EDSP's Tier 1 assessments are available here: https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-edsp-tier-1-assessments

Title: *E.01.3 Interview with Michael Goodis 02/05/2021*

Author:	*Start Date:*	*Completion Date:*	
Natasha Henry	*02/09/2021*	*02/10/2021*	
Reviewer: *LAJ, 2/11/21*			
Review Comments: *wp reviewed and approved. LAJ* *Indexing nh 05/04/21,Added source 4. nh 05/10*			

INDEX A Link: Indexed- remaining background sections.docx

Purpose: *To document information interview with the Michael Goodis to obtain a better understanding of the EDSP management decisions*

Source: *Team notes*

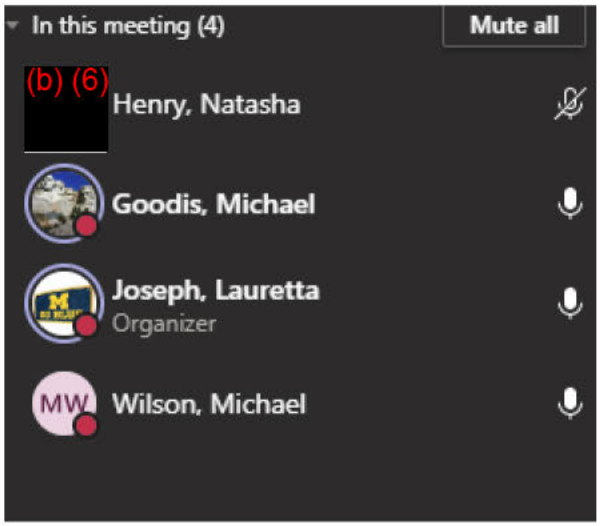
Source 1. Meeting Attendees

EPA

Michael Goodis,
Acting Deputy Division Director OPP

OIG

Lauretta Joseph, Team Lead
Michael Wilson, Team Member
Natasha Henry, Team Member



Source 2. Meeting Information

Friday, February 5, 2021, 10:00 am eastern
Microsoft Teams meeting
Click here to join the meeting
Or call in (audio only)
(b) (6)
United States, Washington DC
Phone Conference ID: (b) (6)

Source 3. Calendar Invite ***Link: OIG Meeting on EDSP.ics***

Source 4. Email ***Link: [R] Interview - Michael Goodis 02/05/21***

From: Goodis, Michael
To: Joseph, Lauretta; Henry, Natasha; Wilson, Michael
Subject: RE: OIG Meeting on EDSP
Date: Friday, February 5, 2021 2:11:11 PM

Also – my reference to the "white paper" is for the following document:
NAMS – new approach methodologies

This document summarizes the scientific progress in the use of NAMs for prioritization and screening of chemicals in the EDSP and lists which NAMs are considered as alternatives to some of the 11 assays in the Tier 1 screening battery or could be considered as "other scientifically relevant information" (OSRI) towards fulfilling certain Tier1 (or test order) requirements.

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
(b) (6) (cell)

Scope: *FWG Interview Section, Step 1*

Conclusion:

On Friday, February 5, 2021, the OIG team met with Michael Goodis via Microsoft teams to discuss general questions regarding the EDSP. He is the acting deputy Division Director for the OPP and is relatively new to the role [details 2]. The reorganization of the EDSP happened relatively quickly and without much guidance or transfer of knowledge [details 5, 17]. They have been focused on communication with staff [details 8] and short to long term goals [details 10, 11]. He was not involved in the prior decision making, so is unable to comment in detail on past happenings [details 15, 16]. He also stressed the importance of the EDSP making a decision on testing [details 19].

If the team decides an interview with (b) (5) [redacted].

Update:
Following the meeting with OIG, Michael Goodis responded to clarify that the below discussion of the "white paper" refers to new approach methodologies for prioritization and screening of chemicals in the EDSP and lists. (Added as Source 4 document).

Details:

Objective-

Introduction:

[1] Lauretta opened the meeting and asked if there were any questions. Hearing none, she said Michael Wilson would lead the meeting. Michael Goodis offered to provide his experience and thoughts on the program, and the team can ask questions during the conversation.

EPA Background:

[2] He is the Acting deputy Division Director for Office of Pesticide Programs (OPP). He has been in this role for half a year and is still in the acting capacity. The reorganization happened and he has only been with the EDSP for a few short months so he has been getting up to speed with the history, and activities of the program. He noted that the program has been going on for decades.

[3] Prior to this role, he was with the Registration Division. He did a detail with OCSP (Office of Coordination and Science Policy) in 2008, where he first gained knowledge of EDSP, but that was in a different time for the program-- when the program was just issuing List 1, Tier 1 test orders. Since then, he has had little interaction with the EDSP.

[4] He reports directly to Ed Messina and is the deputy.(b) (6) [redacted]

Current Status of the program:

[5] The OIG team asked if the reorganization had been in the plans. MG responded that the decision was made higher up the management chain and they were just told of it. There was no conversation. The reorganization was to consolidate most of the mission support functions such as budget, IT, and HR functions. But there were pockets where programs didn't neatly fit-- EDSP was one. This all happened very quickly. There was the notification of congress. Reorgs was more streamlined. Unsure of details.

Integration of EDSP into the pesticide program:

[6] MG continued on-- in some ways, this was a good thing. One difficulty is that the program was in separate office and when one has that-- in addition to being physically separated and working remotely-- this was always a challenge-- how is EDSP being integrated in pesticide program.

[7] One of the goals -- have opportunity to better integrate pesticide work and EDSP work. So there is proper integration and support for good outcomes in reasonable amount of time.

[8] They have had weekly meeting with the entire team-- Anna Lowit, and the heads of the Health Effects Division the Environmental Effects and Fate Division. They have bi-weekly 2 hour long meetings on EDSP to go thorough specific team projects such as the white paper and an update to where they are with the science. They didn't have much involvement before that. There is also a separate meeting on contract funding. A fair amount is allocated to EDSP and there are a lot of contracts for various research. That is new.

[9] He provided an example of a Japanese bilateral agreement. Japan has been engaged in EDSP work for over 10 years. Scott reached out after being contacted by Japanese colleagues and was notified of planning for a bilateral meeting. It went well, but this was a new area of awareness for him.

[10] They (Goodis and Messina) are giving the team direction and asking questions about what they want to accomplish. There are short, medium, and long terms goals. In the short term, their goal is to

finalize the open papers. They would also like to better engage with science divisions and include them in these discussions. That wasn't happening before but that is the right step.

[11] In terms of long term goals, the scope is to address the chemicals beyond pesticides. The EPA team believes that they must address all the chemicals but it is their belief that they have to do it in manageable steps. The office hasn't had that direction-- the scope was so big that they didn't know where to start. They must break it down into manageable tasks. Their first step is to narrow down the pesticides.

[12] Years ago, there was Tier 1 and 2 testing. It took many years and that was only for 50 chemicals. They realized that this pace was unsustainable and they needed to be more efficient. So they called it a "Pivot." They used Computational Toxicology to prioritize.

[13] Michael Wilson (OIG) stated that they white paper was described by MG as the state of the science and where it is going. He then asked if the Tier 2 recommendations would be separate from that. MG responded that he is unsure but the white paper is separate from lists 1 and 2.

[14] MW follow up and asked what the 2015 and 2017 "response to comments" documents were responding to. MG responded that they are dense documents and he would need to review them. These documents were largely developed with a lot of time and effort and they want to bring closure to things that are far enough along. In every meeting, they have the whole team present. Everyone has a seat at the table and can voice their recommendations and concerns. They have been a part of team building and are trying to get everyone on the same page. They are making progress in resolving some science issues that have been out there and have remained unresolved. They don't know where this effort will go but at the end of the day, they want to have a record. There wasn't a roadmap for new managers and they are starting from ground zero.

Tier Testing Orders:

[15] MW asked about List 1, Tier 2.-- What is the plan to close out because right now it exists out there. MG responded no. He wasn't involved in the decision making so that is hard to answer. He can speculate (b) (5) .

[16] MW asked about list 2? MG responded that this is the same thing. That approach is too massive and unsustainable. His sense is (b) (5)

Comprehensive Management Plan:

[17] MW asked if management is using a version of the CMP (comprehensive management plan) or something else? MG said that he was unaware of the CMP until this audit was initiated and wish they had known about it during the transition. They received scientist who were working on many different things and the handoff wasn't smooth. There wasn't any "here is out management plan, budget, completed tasks, and upcoming deadlines."

Additional Questions:

[18] LJ asked if EDSP was a program versus a compilation of activities.

MG answered that there was a lot of work that had been done. Anna Lowit plugged in to some degree. But his observation was that this was a program initiated in 1996, so over 20 yrs. His perspective-- they do science determinations, registration and evaluation. And always shared with his staff is there all work and decisions is great if that stuff is not on pesticide label-- otherwise just academic. If doesn't get onto label, its meaningless.

[19] (b) (5) [redacted]

[20] Look at this program, unaware of anything that came out that actually ended up on label. Trying to achieve-- done a lot of work, a lot of science, research and challenge is trying to integrate it where they can-- is there data, science that is important to consider for how they are regulating pesticides. Being managed separately.

[21] MW asked if there was a test requirement for new pesticides coming in. MG said that this still comes back to issues they've had before. It is a two-step process that takes years and they have to determine which the best way to implement is.

[22] He provided an example of the endangered species program. It is better to deal with the re-evaluation stage-- at least in that effort they are generally looking at chemicals as class in a group.

[23] One issue that comes up-- unless have full program laid out with implementation. And putting information on the label. Bu t competitors don't have that and now find themselves on a list and its 20 years before you get to them. – He isn't saying to not do the testing, but is mindful of having a level playing field for the regulated community. They (EPA) want to have a program that can be implemented broadly and fairly. Availability of products impact, etc.

INEDX B Link: Indexed- Results- IC.docx

Full Time Equivalent (FTE) staff:

[24] MW asked about FTE (referring to full time equivalent staff). MG said that the program staff is smaller than it used to be. There is no detailed budget plan. This is still new for him and he is still figuring out where they are with the program. There is a lot of money going out in contracts for research and they need to make sure that those activities are still a priority and will contribute to EDSP in a way that is needed. There is a learning curve.

Performance Measures:

[25] MW asked what performance measures do they think they (EPA) will use for EDSP. MG responded that although that is a good question, this program is different as a research development program where outcomes are long term. Ideally there would be on stage where they can do screening but not at that stage. He wondered aloud on how much millions have been spent and what they got for the money. This is part of the challenge.

[26] NH asked if the team had the correct description of the programs evolution from EDSP to EDSP21 to the Pivot. MG responded that he is unsure and the OIG would need to ask Stan Barone.

[27] MW asked if there was any direction on performance measures from OCFO (Office from the Chief Financial Officer). MG responded no.

[28] LJ asked who the team should speak with. (b) (5) [redacted]

The meeting concluded.

Author: LAJ	*Start Date: 2/06/21*	*Completion Date: 2/11/21*	
Reviewer: Erin Barnes-Weaver, 3/5/21			
Review Comments: Reviewed and found satisfactory and added bookmarks/links to the conclusion. *Indexing. nh 05/04/21, 05/17.*			

Purpose: To document interview with Office of Pesticide Programs (OPP) director, Ed Messina, regarding status of Endocrine Disruptor Screening Program (EDSP)

Source: Interview notes

Source 1- Meeting invite

Scope: Fieldwork; Section

INDEX A Link: Indexed- remaining background sections.docx

Participants:

Ed Messina- Acting Director, OPP, 703-(b) (6)
Lauretta Joseph- Team Lead, OIG- NY, 212-(b) (6)
Natasha Henry- Health Scientist, OIG -NY, 212(b) (6)
Michael Wilson- Toxicologist, OIG-HQ, 202(b) (6)

INDEX C Link: Indexed- Results- IC.docx

Conclusions:

In order to move forward there are items that the current director wants to be completed. Namely, the white paper and 2015 and 2017 response to comment documents. [See EBW_1] **There are differences in opinion on the path forward so there are several management decisions that need to be made regarding testing and what meets the requirements. The EDSP needs to determine how many staff it should have to run the program.** [See EBW_3 on FTEs] **The EDSP does not have performance measures. The EDSP does not have a planning document and has not conducted internal or annual reviews.** [See EBW_2 on no strategy document]

OIG conclusion: EDSP is not functioning effectively. The EDSP does not have needed internal controls to manage an effective program.

DETAILS:

(Author notes- teal highlights are for emphasis. Yellow highlights are for items that are incorrect or incomplete.)

Introduction- Lauretta started off the meeting by stating our objective to learn more about the status of the program and the path forward. Instead of following straight through the questions, Ed offered to just speak freely and we could ask question as needed. The team agreed that this was a reasonable plan.

Ed- I appreciate the work you are doing. I acknowledge that there is work to do in regards to the EDSP. As acting director, my focus has been a few main things including "How to integrate the EDSP into the agency- this is the piece that I am grappling with"
A lot of work has been done over the years, Link: Indexed- Results- IC.docxhowever EDSP needed direction and (b) (5) [redacted]. I have started meeting with EDSP each week (b) (5) [redacted] My approach has been – to have the team break work down. Tell me what they will do in the short term (this week), mid term (next few weeks), and long term (month). PM note: OIG notes that prior to the reorganization in October 2020, EDSP did not have short, mid, or long term goals.

Ed-In order to move forward there are things that we need to finish out that have been started before I became director. The things that we need to finish 1) the white paper- it has been in production for 5 years- let's finish it! Part of why it hasn't been finished is that there are folks on the team that really want to get things right so there is always something more to do. So there are decisions that senior leadership needs to make on when it is considered done. However, I feel like the team has made progress on the white paper- and it is about 95% done (according to Anna Lowitt, science advisor). There are 3 or 4 issues we still need to make decisions one. Lastly there are the 2015 response to comment document and 2017 response to comment document. I want those finished also. Joe has finished one of those documents and it is now under review.

Ed- I also want to mention the pivot document. (b) (5) [redacted] We need to have a strategy doc for where we need to go and that is the next document that needs to get done. Within this larger strategy document we need to parse out how does OPP satisfy its obligation under the statute. Link: Indexed- Results-EDSP.docxQuestions such as (b) (5) [redacted]
PM note: OIG notes that because prior management did not make these decisions, current management is having to make decisions on what test orders to issue and what controls need to be implemented.

Ed-We believe that there is a lot of work that we have done and are doing and that work should count toward the goal. But we haven't been documenting or taking into account that in regards to a strategy.
INDEX D Link: Indexed- Results- IC.docx
Natasha- How does EDSP incorporate other chemicals like SDWA?

Ed- the next step is endocrine chemicals. (b) (5) . (b) (5) and making sure we are funneling up through agency offices.

Michael- according to congress all pesticides have to be done; In our original EDSP staff meeting it was stated that it is then left to the Administrator to decide on the "other chemicals" so there is a lot of leeway.
Ed- If we (OIG) has advice for that please provide. We want to know - (b) (5) (b) (5) Once we get through the white paper and other items this is an important area of discussion.

INDEX A Link: B.07.2 EDSP Budget and FTE .docx Link: Indexed- Results- IC.docx
Ed- We have 4 or 5 FTE; but now looking at the dollars; I am starting to ask how many should I get. I heard that I should have about 8 FTE. You all should speak to (b) (5) where are these FTE going. You will have to start asking up the chain. The question remains- are we using the FTE that congress asked us to use to run this program? There is a lot of dollars going to contracts. We recently had a long contracts meeting. We get a decent amount of $ in contracts. There is a lot of money that is already out there being spent on this work for us. I also want to make sure we are being strategic about forwarding the science that is going to help the program. Trying to be more targeted in managing the program.

Michael- it is hard to understand how many have been approved under Tier 1 battery.
Ed- Depending on who you ask, you will get different how much are NAMS going to play into the review of EDSP. (b) (5) Normally you can feed to the animal or the cells, and now you can feed it to a computer model. Now instead of having to do a 100 rat studies you can run a high computational throughput. Kristan is working on predictive analytics and AI. With this method, you put in the computer and trust the AI to get it right. But to answer your original question, that is the science debate that the team needs to have, which NAMs are relevant. There are some assays that folks all agree that NAMs are appropriate. I won't give my answer right now.

Lauretta- Looking at the EDSP. Did you feel that you were handed a functioning program or a bunch of activities?
Ed- the program got split up a little with the reorg. I only got some of the folks from the original EDSP. To get the forensics and the history, I decided to have past staff participate. For example, Sharlene. (b) (5) Main thing to determine was what direction did EDSP have previously. Did they feel empowerment? Overall, staff felt that the Agency was not doing what it was supposed to do.
Previous role was _____. As acting director for OPP, I am managing over 600 people.

Ed- Going back to short term goals- under pesticide registration review process- we open a docket. DCI A lot of our final decisions may not have ED as a part of the 2022 deadline. We need to get the strategy done in the next few months in order to make the decision. If we identify chemicals, then we have to DCI to industry. We already working on round 2 chemicals.

Michael- Is any of the endocrine disrupter data used for initial registration for pesticides?
Ed- The answer is there is some data that would count toward EDSP. For specific examples talk to Anna but we have not determined or have an SOP for what that is for the office.

Ed- for List 1 Tier 2- there is a difference of opinion between previous EDSP staff, Anna, and OGC. (b) (5) [redacted]

Author- did not get this statement in context- (b) (5) [redacted]

Michael-List 1 you have wildlife studies. How do you plan to close out what has already been published- how are you going to close out Tier 1- will you be sharing the information?
Ed- Yes, there will be a transparent document. Most everything is publicly vetted. We need to tell registrants what they need to satisfy. Everything will be notice and comment. We are used to being open and transparent. Yes, we still have to close out List 1 Tier 2.

Ed- There are existing public statements that are there but they are still draft. Again the next steps are to finalize the white paper, finalize the 2015 response to comment document and the 2017 response to comment document. That will provide the background. The pivot document and new strategy will tell folks how to get where we need to be and how OPP will satisfy its requirements under the EDSP. Short term and long term we also will need a document that states how the EDSP will work with the rest of the agency. But to respond to you, we are going to make decisions around the lists.

Michael- what is the plan for List 2- how do you close out
Ed- all I know there was a lot of work done and decisions were not made. CMP is not really something I know about, We can speculate on why is was not finalized.
Ed- moving forward we may (b) (5) [redacted]

Lauretta- There are not currently and performance measures for the program. Is there are plan to have measures as you move forward.
Ed- Performance measures-yes, but I guess output measures to start because it could be difficult to have outcome measures. We have some already.
Natasha- making sure I understand, when you say there are performance measures, do you mean for OPP or EDSP?
Ed- Overall OPP measures but not specific for EDSP.

Ed- there is a difference of opinion (b) (5), (b) (6) [redacted].

Michael- so there is a difference of opinion (b) (5) [redacted]
Ed- yes but as part of the strategy (b) (5) [redacted]

Lauretta -Once the program received funding from Congress each year, did the OCFO provide you with guidance and/or procedures for how your program should proceed such as how you would meet ongoing implementation requirements, as well as data collection, annual measurement and annual reporting requirements?
Ed-Speak to (b) (5) [redacted]

INDEX B Link: Indexed- Results- IC.docx
Lauretta- It is unclear whether the EDSP continues to develop annual reviews as recommended by the OIG or if they do any internal reviews.
Ed- I do not know of any reviews.

Suggestions on people to speak with:

- (b) (5) [redacted]
- [redacted]
- [redacted]

Lauretta closed the meeting. Ed offered to speak to us again if needed.

Meeting ended at 9:05am

From: Goodis, Michael
To: Joseph, Lauretta; Henry, Natasha; Wilson, Michael
Subject: RE: OIG Meeting on EDSP
Date: Friday, February 5, 2021 2:11:11 PM

Also – my reference to the "white paper" is for the following document:
NAMS – new approach methodologies

This document summarizes the scientific progress in the use of NAMs for prioritization and screening of chemicals in the EDSP and lists which NAMs are considered as alternatives to some of the 11 assays in the Tier 1 screening battery or could be considered as "other scientifically relevant information" (OSRI) towards fulfilling certain Tier1 (or test order) requirements.

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
(b) (6) (cell)

From: Joseph, Lauretta <Joseph.Lauretta@epa.gov>
Sent: Friday, February 05, 2021 12:24 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>; Henry, Natasha <Henry.Natasha@epa.gov>; Wilson, Michael <Wilson.Michael@epa.gov>
Subject: RE: OIG Meeting on EDSP

Thanks Michael. There was no embarrassment at all. If anything, thanks for not holding us to knowing all the perfect terminology!

Have a great weekend and thanks again for your time this morning.

Lauretta

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Friday, February 5, 2021 12:13 PM
To: Joseph, Lauretta <Joseph.Lauretta@epa.gov>; Henry, Natasha <Henry.Natasha@epa.gov>; Wilson, Michael <Wilson.Michael@epa.gov>
Subject: RE: OIG Meeting on EDSP

In an attempt to recover from some embarrassment of not knowing specifically to which comments we were developing responses, the following I hope answers your question.

This "Response to Public Comments" document provides a summary of the comments specifically received on, and related to, EPA's plan to incorporate an alternative scientific approach to screen chemicals for their ability to interact with the endocrine system, and the Agency's responses to those comments. EPA published the request for public comments on EPA's plan in a June 19, 2015 Federal Register Notice (80 FR 35350).

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
(b) (6) (cell)

-----Original Appointment-----
From: Joseph, Lauretta <Joseph.Lauretta@epa.gov>
Sent: Thursday, January 28, 2021 5:34 PM
To: Joseph, Lauretta; Goodis, Michael; Henry, Natasha; Wilson, Michael
Subject: OIG Meeting on EDSP
When: Friday, February 05, 2021 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

Thank you for arranging to meet with us. We look forward to our discussion with you.

Lauretta

Microsoft Teams meeting

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Author: MHW	Start Date: 2/10/21	Completion Date: 2/26/21
Reviewer/Date:	LAJ/ 3/3/21	
Review Comments: great wp. Wp reviewed and approved. LAJ		
Edited by: Indexing, NH 05/10/21, 05/17.		

Title: Interview – Sharlene Matten (2 9 21)
Workpaper: E.1.6

Purpose: To document the OIG's interview of Sharlene Matten (i.e., former EDSP Director and former senior EDSP scientist)

Date / Time / Location: Tues., Feb. 9, 2020/ 1:00 pm – 2:00 pm/Microsoft Teams Meeting

Participants/Invitees:

OIG / Office of Evaluation (OE)
Lauretta Joseph, Project Manager, OE/Toxics, Chemical Mgt. and Pollution Prevention (TCMPP)
Natasha Henry, Auditor, OA&E/TCMPP
Michael Wilson, Toxicologist, OA&E/TCMPP

Office of Chemical Safety & Pollution Prevention (OCSPP)/Office of Pesticide Programs (OPP)
Sharlene Matten

Source:

Source 1: OIG Interview Questions for Sharlene Matten
Filename: E.1.6 - Source 1 - sharlene_interviewquestions.docx

Scope: The scope of this workpaper is limited to documenting the OIG's discussion with Sharlene Matten on Feb. 9, 2021.

Conclusions:

- SM believed (b) (5) [redacted]
- SM stated EDSP testing was never a priority to EPA management.
- SM stated that EDSP needs a plan of where we go from here.
- SM stated that since 2016, there is no plan how we are going to use this new technology.
- SM stated that "Everything in EDSP came to a full stop in 2016."

- SM expressed that "In OPP's opinion, OPP does not see a need to complete the EDSP testing because the current toxicity studies required by 40 CFR 158 adequately characterizes the risk from endocrine disruption."

- SM stated that the OIG could get a copy of the "white paper" that she is working on.

- SM expressed that the current pesticide review program will not be able to evaluate endocrine disruptor activity due to the lack of data and we will have to wait 15-years for the next cycle of the pesticide review program.

- SM suggested that the Agency should require the EDSP data to be regenerated and submitted as new pesticides are registered.

- SM stated that OSCP comments on OPP's 2019 Re-evaluation of the List 1 -Tier 1 data were NOT draft, but final comments.

- The 2015 Response to Comments document has been around for 6 years. It has been done since 2017, but EDSP could not get management's approval on our response.

- The 2017 Response to Comments document has been around for 4 years.

- For the 2015 and 2017 Response to Comments, there is a disagreement on the predictivity of the high through put assays with real world results.

- OPP ecological risk assessors are only interested in apical results (e.g., adverse effect on survival, organ weights, or decreased reproduction).

- OPP's 2019 re-evaluation of the List 1 - Tier 1 did not follow EPA's Weight-of-Evidence (WoE) approach for evaluating the need for Tier 2 data. OPP's 4-step process does not meet EPA's requirements for evaluating EDSP data.

- EFED's 2019 re-evaluation concluded that 0 out of 17 pesticides need Tier 2 testing. (b) (5), (b) (5) [redacted]

- OCSP and EFED had no formal interaction concerning EFED's 2019 re-evaluation.

- EFED did not consider OCSP's scientific comments on EFED's 2019 re-evaluation of the List 1 – Tier 1 data.

Results:

LJ – Provided introductions. LJ gave SM the option to just talk what she thinks the main issues or do you want us to go done our prepared list of questions.

[Analyst Note: (b) (5)]

INDEX B Link: Indexed- Results- IC.docx

SM – I wish to be succinct. Link: Indexed- Results-EDSP.docx **Ref A** I believe (b) (5) SM stated that EDSP testing was never a priority to senior EPA management (b) (5)

LJ – EDSP issued two CMPs, but never issued another. Do you think OPP needs to develop and issue a current CMP?

SM – You ask about EDSP CMP. Yes. EDSP needs a plan of where we go from here.

SM – We tried to spent money as best as we could.

SM – You should talk to my two contacts in OGC [she gave names, but too fast to write down. The second (b) (5) .] You should see the OGC memo that was requested (b) (5) .

LJ – We have a copy.

SM – (b) (5), (b) (6)

LJ – Could you give us a brief history of the EDSP from your experience.

SM – Wrote a book chapter on the topic. Bill Wooge set up a nice table providing a history of the program. It started with the 1996 FQPA. The issue was how to create a program? The FACA was formed that recommended how the program should be designed. The federal advisory panel expanded the Congressional mandate to include not just estrogen effects, but also androgen and thyroid effects. The FACA process was really transparent.

SM – How to select the chemicals for EDSP was the next question? It took years. It was slow but was inclusive.

SM – Another issue was the development of the Tier 1 and Tier 2 tests. To get them developed and validated took to June 2013 [i.e., 2009 for Tier 1; 2013 for Tier 2]. Then it was identified that these tests consumed a lot of animals to perform. Animal testing has become distasteful. EPA could not realistically conduct animal testing on 70,000 chemicals.

SM - We have to evolve through the use of high through-put (HTP) assays and computational toxicity to avoid killing animals. This effort started with the Tox-21 plan. In 2012, Congress told EPA to shift to testing a narrower set of chemicals (i.e., less than the 70,000 chemicals).

SM – Since 2015, the EDSP performance plan was just about the development and validation of the HTP assays and computation toxicity methods. It took five years to get 3 HTP assays reviewed and approved for Tier 1 data. EPA approved the use of the 3 HTPs in 2015.

SM – Since 2016, there has not been a plan how EPA is going to use this new NAMs technology. As a result, everything in EDSP came to a full stop in 2016. INDEX H Link: Indexed-Progress and Testing.docx Link: Indexed-Progress and Testing.docx Link: Indexed-Results-EDSP.docx **Ref B** Due to the lack of senior OCSPP management making any EDSP program decisions, OCSPP leaders stopped the process of issuing any test orders to List 1 – Tier 2 and List 2 – Tier 1.

SM – Registration Review (RR) has to review existing registration every 15 years. At the beginning of the process, RR has to formulate their data needs.

SM – There was little discussion between OCSP/EDSP and OPP. The few discussions OCSP/EDSP and OPP had, we disagreed what needed to be done with endocrine disruptor testing. The legal language of section 408(p)(3) does not provide a specific timeframe in which testing of all pesticides for endocrine disruption has to be completed by. In OPP's opinion, OPP does not see a need to complete the EDSP testing because the current toxicity studies required by 40 CFR 158 adequately characterizes the risk from endocrine disruption. (b) (5) [redacted]

SM – Now RR has about 1000 registration reviews due and how they are scrabbling how to make this mandate happen.

SM – I am currently working on the "white paper" that identifies how OPP is going to use this new technology (i.e., HTP assays and computational toxicology).

SM – SDWA has other process. OPP is not working on the SDWA chemicals. You will have to talk with our management how they are going to implement the testing of the SDWA chemicals.

SM – When all EDSP work stopped in 2016, (b) (6), (b) (5) [redacted]

MW – If I can jump in. Can I ask you to descript what you are currently working on? We have been told that the ESDP is completing three tasks: two response to comments and a white paper.

SM – I am working complete the Response to Comments on the 2017 Science Advisory Panel recommendations advancing some more of the NAMs technologies. They will be used in the prioritization process for those pesticides that need to be screened first. (b) (5), (b) (6) [redacted]

SM – I am also working on a white paper. It is still in draft. I have only some minor edits to make to the file.
MW – We would like to see a copy of the draft. During our interviews, the interview would talk about this white paper, but we have not seen a copy. We have asked for it during the entrance conference. We asked for it from Bill Wooge, but he referred us to you since you are apparently the keeper of the document.

SM – Yes. You can have a copy if you don't mind my editorial comments still in the Word document. You know I am a perfectionist and pay a lot of attention to the details and want it to be correct.

MW – We don't mind. We understand it's a draft. We understand it's not a final decision of the Agency. We just want to see the latest version so we can get an idea of what the general content, nature, purpose of the document.

SM – Let me finish a few last-minute issues and I can seen it to you later in the week.

SM – The last thing I am working on is the Response to Comments on the 2015 Science Advisory Panel recommendations. It has been done since 2017, but we can't get management's approval on our response.

LJ – LJ asked SM in her opinion what changes could be made to improve the EDSP program.

SM – The pesticide review program has to complete the assessment of about 1000 pesticides on a tight schedule. OPP is not going to get any EDSP endocrine disruptor for this cycle of the pesticide review program. We will have to wait for another 15-years to get EDSP endocrine disruptor data included in these reviews.

SM – A big administrative problem is just getting the EDSP data. [Analyst Note: (b) (5) [redacted] The Agency should require the EDSP data to be regenerated and submitted as new pesticides are registered.

SM – In regards to the transition of EDSP from OSCP to OPP, OPP is not scientifically concerned with the need to collect Tier 2 data. While in OCSP, I generated EDSP's comments on OPP's 2019 re-evaluation of List 1 – Tier 1 data. I identified that there is a serious scientific disagreement and recommended the issue be sent to a FIFRA Science Advisory Panel. (b) (5), (b) (6) [redacted]

MW – Where those draft comments every finalized?

SM – They were not draft comments.

MW – I thought the header said draft. Let me check my copy. After finding my copy, I read the header – "Internal Planning Document – Do not cite, Quote or Release – 9/17/2019". Your correct. That does not say draft.

SM – (b) (5), (b) (6) [redacted]

SM – Before I am no longer part of the EDSP effort, what do you do with all the money let on contracts for develop of EDSP methods. I want to figure out how to best use the money to generate a method that will actually be used.
INDEX B Link: Indexed- Results- IC.docx
MW – The 2015 Response to Comments documents have been around for 6 years and the 2017 Response to Comments have been around for 4 years, what the hold up in getting the approved and out the door?

SM – For the 2015 and 2017 Response to Comments, there is a disagreement on the predictivity of the high through put assays with real world results. Specifically, how well the uterotrophic assays for estrogen disruption predict real world observations. Furthermore, the uterotrophic assays do not evaluate the chemical's metabolites.

> [Analyst Note: In toxicity testing, one needs to test both the parent compound and its major metabolites in order to evaluate the toxicity of the chemical, because the metabolite is often the xenobiotic that is the toxic component. If the HTP assay only test the toxicity of the parent compound and not the metabolites, the method misses collecting half the data.]

SM – For the uterotrophic assays, some compounds can't be tested by these new methods. For example, how do you test a gas, when the test only accepts chemicals in liquid form (e.g., dissolved in liquid) or the chemical is a solid that will not dissolve in a liquid.

SM – One problematic issue is the perception that the registrant has to conduct the testing. It would be a lot more efficient if EPA just conducted the test. (b) (5), (b) (6) [redacted]

SM – Another issue is OPP preference to use only data from the 40 CFR 158 guideline studies. (b) (5) [redacted]

SM – Another big problem is the commercial ability to perform these EDSP HTP assays. ORD developed the method, but there is no commercial capacity to perform the test anymore. (b) (5) [redacted]

> [Analyst Note: (b) (5) [redacted]

SM – In SM's opinion, (b) (5) [redacted]

SM – SM stated that its probably (b) (5) [redacted].

SM – SM state (b) (6), (b) (5) [redacted].

SM – Another problem is (b) (6), (b) (5) [redacted].

SM – Another twist to the issue is EPA Administrator Wheeler's policy directive that EPA will not fund mammalian studies by 2035. Anna Lowit leads OPP's NAMs development in her role as science advisor. EPA is working to replace the animal testing in the 40 CFR 158 data requirements, but EDSP tests are not in the road map for NAMs development. SM referred us (b) (6) [redacted] for more information on this topic.

LJ – Who is the holder of the strategic plan for EDSP?

SM – We have a draft and it is under management review.

LJ – What was the process of reviewing and approving a CMP?

SM – In OCSP, we would get staff concurrence then seek management approval. It would have been simea' [name misspelled] or Stan Barone. In OSCP, we had a written process for the development and issuance of the CMP. We might have briefed the AA regarding the CMP. The process worked all the way up to 2015. Since 2016, we have had major conflicts among staff and between staff and management.

SM – SM identified that she monitored the EDSP budget from 2015 through 2019. She used EPA's Compass Data Warehouse data to track where EDSP's money was being assigned. SM presented large spreadsheets itemizing where all the EDSP money was budgeted for on what research activities from about 2015 to 2019. SM stated that EDSP was two-year money that was spent on NAM method develop.

> [Analyst Note: I think (b) (5) [redacted]

MW – Could you explain OCSP's comments/issues with EFED's 2019 re-evaluation of the List 1 – Tier 1 data?

Link: B.03.1 EDSP Tiered Assessments .docxSM – In a risk assessment, you need to determine whether a chemical poses a particular hazard. In this case, EDSP Tier 1 data determines whether a chemical poses a hazard to one of the endocrine systems (e.g., estrogen, androgen, or thyroid). If the chemical poses a potential hazard, then the EDSP Tier 2 data is designed to quantify the

risk by producing a dose-response curves. A dose-response curved is then used in a risk assessment to determine whether real world exposure levels pose a risk to human health or the environment.

SM – EDSP Tier 1 evaluates whether a chemical can interact with the endocrine system. It is mechanistic data. The data evaluates the potential disruption of a single biological step. The studies are designed to evaluate this biological step.

SM – By contrast, OPP ecological risk assessors are only interested in apical results (e.g., adverse effect on survival, organ weights, or decreased reproduction). An OPP risk assessment is not interested in EDSP's mechanistic data regarding the endocrine system. In OPP's opinion, if the biological effects are not large enough or adverse enough to be observed in the apical effects then its not significant enough to trigger the FIFRA's regulatory requirement of producing an "unreasonable adverse effect" on the environment. Therefore, in OPP's opinion, OPP does not see the need to collect additional EDSP Tier 2 data.

[Analyst Comment – (b) (5) [redacted]

SM – However, OPP's 2019 re-evaluation of the List 1 - Tier 1 did not follow EPA's Weight-of-Evidence (WoE) approach for evaluating the need for Tier 2 data. OPP's 4-step process does not meet EPA's requirements for evaluating EDSP data.

SM – EFED's 2019 re-evaluation is not a balanced comparison. EFED mixes up different statutory authorities. EFED can not exclude hazard identification from risk assessment.

SM – For 2 or 3 pesticides, EFED substituted a fish study for an amphibian study that was not available.

SM – EFED's 2019 re-evaluation needs a lot of rework to be done. EFED's 2019 re-evaluation lacks scientific support that it poses a scientific integrity question. In OCSP comments on EFED's 2019 re-evaluation, we identified 5 pesticides that are "high need" of additional Tier 2 data. However, EFED's 2019 re-evaluation concluded that 0 out of 17 pesticides need Tier 2 testing (b) (5), (b) (6) [redacted] EFED is "not asking for more data" before conducting their risk analysis. OCSP and EFED had no formal interaction concerning EFED's 2019 re-evaluation.

SM – EFED did not consider OCSP's scientific comments on EFED's 2019 re-evaluation of the List 1 – Tier 1 data. I was not able to provide redline-strikeout comments. OCSP's comments were just presented conceptual issues. (b) (5), (b) (6) [redacted]

SM – The OSCP's comments recommended that EFED's 2019 re-evaluation be sent to a FIFRA science advisory panel (SAP). A FIFRA SAP would not be biased in either direction (i.e., OSCP or EFED's approach).

SM – EFED's 2019 re-evaluation does not address endocrine endpoints. EFED's risk assessments need to look at all endpoints not just endocrine endpoints. EFED's 2019 re-evaluation does not have any resolution of the hormonal effects observed in the List 1 – Tier 1 data.

INDEX A Link: Indexed- Results- IC.docx Link: E.01.1 - [R] Interview with EPA 01/26/21 - wp details.docx

NH – I have a quick question. Did EDSP conduct annual reviews or internal reviews of the program?

SM – (b) (5), (b) (6) [redacted]

LJ – Do you have anything else you would like to say?

SM – (b) (5), (b) (6) [redacted]

SM – I have to go. I have another meeting at 2 pm.

LJ – If we have additional questions, are you available for say another 30 minutes?

SM – Yes. Just fine an opening on my schedule.

Everyone – Said their good-byes.

Questions for meeting with Past EDSP Director
Tuesday, February 9, 2020 at 1pm
Microsoft Teams Meeting

Evolution of EDSP

1. Please remind us of your current and previous roles in EDSP.
    a. ~~Please discuss the previous organizational structure of the EDSP.~~
    b. Would you discuss the evolution of the EDSP structure within the EPA organizationally?
    c. In your experience, where should EDSP be housed to best serve the Agency?
2. Please discuss the status of the incorporation of EDSP into the pesticide registration review process.
3. The draft 2018 Comprehensive Management Plan (CMP) identifies the expected "achievements" for the next two years assuming adequate funding and staffing. This planning takes EDSP to April 2020. Since April 2020, what plan has management been using to guide or task EDSP activities?
4. ~~To your knowledge, why was the draft 2018 EDSP CMP not finalized and approved?~~
5. Would a policy or procedure that guides the process for management's review and approval of the CMP (or a similar strategic planning document) be useful?

List 1 – Tier 2 Test Orders

6. EPA has not issued any test orders. On Aug. 3, 2015, EPA provided OMB with the ICR for the List 1 – Tier 2 test orders.
    a. ~~Please describe EPA's actions to get OMB's approval.~~
    b. ~~What was OMB's reasons for not approving EPA's ICR? Any records documenting OMB's reasons for denying or returning of the ICR?~~
    c. When did OMB formally deny/return the ICR to EPA? Any records documenting OMB's denial/return of ICR?

7. On Sept. 17, 2019, Office of Science Coordination and Policy (OSCP) provided scientific and policy analysis comments on the white paper. What actions, if any, did OPP take regarding OSCP/EDSP's comments on the white paper?

8. Please describe the purpose of the 2015 and 2017 response to comment documents and their current status.

List 2 – Tier 1 Test Orders

9. ~~The final EDSP List 2 was published on June 14, 2013 (78 FR 35922). The EDSP List 2 originally contains 109 Chemicals (41 pesticides and 68 SDWA chemicals). The 2014 EDSP CMP states EPA will incrementally issue these test orders over 3 years from 2014-2016. Furthermore, the 2014 EDSP CMP~~

identifies it will take another year for the EPA to review the data, but also identifies a period of activity spanning 2016-2019.

a. Please explain why EPA has not issued these List 2 Tier 1 test orders for the 107 chemicals/pesticides remaining on the list?

b. With EDSP moved into OPP, what role does EDSP perform in the testing of chemicals regulated outside of OPP (e.g. the 68 SDWA chemicals on EDSP List 2)?

c. Specific to the SDWA chemicals, has a determination been made to not conduct EDSP Tier 1 testing?

10. In the 2009 House Report #111-180, Congress instructed the EPA to issue 25 test orders per year from List 2 starting in FY'11. Why has the EPA not complied with this direction from Congress?

11. Overall, what have been the barriers to EPA conducting the testing that Congress mandated?

Performance Measures and Reviews

12. Although the program was cancelled in the presidential budget the last four years, it has subsequently been funded by Congress each year. As a funded program, why does the EDSP not have any current performance measures?

13. Once the program received funding from Congress each year, did the OCFO provide you with guidance and/or procedures for how your program should proceed such as how you would meet ongoing implementation requirements, as well as data collection, annual measurement and annual reporting requirements?

14. To your knowledge, has EDSP conducted any internal reviews of the program or any annual reviews as specified in the OIG's 2011 report recommendations?

15. According to the corrective actions agreed to with the OIG for the 2011 report, EDSP was to conduct annual reviews. Provide an overview of the most recent annual review, including any challenges, and major findings.

a. How frequently are these reviews conducted?

b. Have there been communication challenges that were noted between staff and upper management?

c. When is the next review scheduled to be conducted?